

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 02419
LITIGATION)	Docket No. 1:13-md-2419-RWZ
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This document relates to:)
)
Handy v. Box Hill Surgery Center, LLC, et al.)	
No: 1:14-cv-14019-RWZ)	
)
Armetta v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14022-RWZ)	
)
Torbeck v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14023-RWZ)	
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Kashi v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14026-RWZ)	
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Bowman v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14028-RWZ)	
)
Dreisch v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14029-RWZ)	
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Davis v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14033-RWZ)	
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Farthing v. Box Hill Surgery Center, LLC, et al.)	
No. 1:14-cv-14036-RWZ)	

**BOX HILL DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT
CONCERNING PLAINTIFFS' MASSACHUSETTS CONSUMER PROTECTION
CLAIM**

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhamhani, M.D., and Ritu T. Bhamhani, M.D., L.L.C. (hereinafter, collectively “Defendants” or “Box Hill Defendants”), by undersigned counsel, submit this consolidated memorandum of law in support of their motion for

summary judgment regarding Plaintiffs' Massachusetts consumer protection claim in each of the Box Hill cases.

I. INTRODUCTION

In each of the above captioned cases, Plaintiffs asserted claims alleging that Defendants violated Massachusetts consumer protection laws. Defendants now move for summary judgment on the Massachusetts consumer protection claim in each case as it is not a proper cause of action in these cases and Defendants are entitled to judgment as a matter of law.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which otherwise do not apply to the singular claim addressed in this motion for summary judgment.

In short, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue. NECC shipped their drugs to health care providers all across the country who administered the drugs to their patients using their own medical judgment. The Defendants reside and work in Harford County, Maryland. The patient Plaintiffs received the care at issue at Box Hill Surgery Center located in Harford County, Maryland. None of the care at issue occurred in Massachusetts. None of the patient Plaintiffs are/were residents of Massachusetts either.

Plaintiffs Massachusetts consumer protection claims were made against Maryland Defendants by Maryland, or at least non-Massachusetts, residents in Maryland state courts.¹ The instant Plaintiffs' claims against the Box Hill Defendants are governed by Maryland's Health Care Malpractice Claims Act (hereinafter "HCMCA" or "Act"), codified in Md. Code, Cts. & Jud. Proc.

¹ These particular MDL claims were made in the Circuit Court for Baltimore County, Maryland, while other claims by different plaintiffs against the same Box Hill Defendants were made in the Circuit Court for Harford County, Maryland.

Art., 3-2A-01, *et seq.* The Act establishes requirements that must be satisfied in order for a plaintiff to proceed with a civil action against a Maryland health care provider for claims involving medical care. Plaintiffs complied with the requirements of the Act. The cases were then removed to this Court and consolidated with this multidistrict litigation by action of a now settled co-defendant. The Box Hill Defendants had no involvement in the requested removal.

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment as to the Massachusetts consumer protection claims in all cases because it is clear that this claim is not properly brought pursuant to Massachusetts statute.

II. STATEMENT OF FACTS²

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").³

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).⁴

3. The Plaintiffs' claims against the Box Hill Defendants arise from alleged injuries suffered from potential exposure to MPA administered by Dr. Bhambhani and the Box Hill Defendants while performing epidural steroid injection procedures.⁵

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.⁶

² The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.

³ Dreisch Complaint at 3, ¶ 1.

⁴ Dreisch Complaint at 17, ¶ 51.

⁵ Dreisch Complaint at 37, ¶ 145.

⁶ See Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center (“NECC”) even in just the five months preceding the meningitis outbreak at issue.⁷

6. NECC was regulated and inspected by the U.S. Food and Drug Administration (“FDA”).⁸ In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that “the Federal Food, Drug, and Cosmetic Act (“FDCA”) establishe[d] agency jurisdiction over ‘new drugs,’ including compounded drugs.”⁹

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Womens Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.¹⁰

8. After receiving orders from healthcare providers like Dr. Bhamhani, NECC failed to “follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure,” failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce “sterile” drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.¹¹

⁷ See NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.

⁸ See FDA Warning Letter, attached as **Exhibit 3**.

⁹ *Id.*

¹⁰ See Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women’s Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women’s Vendor Audit Survey Form, attached as **Exhibit 6**.

¹¹ Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64.

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.¹²

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.¹³ As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.¹⁴

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.¹⁵

12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.¹⁶

13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.¹⁷ Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.¹⁸

¹² See Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; see also Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

¹³ *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

¹⁴ Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

¹⁵ See Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

¹⁶ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

¹⁷ See Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.

¹⁸ See *id.*

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.¹⁹

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.²⁰

III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is “entitled to judgment as a matter of law” when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id.* at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id.* at 324. To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth “specific facts showing there is a genuine issue for trial.” *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

IV. LEGAL ARGUMENT

In Count 9 of Plaintiffs’ Complaints, Plaintiffs assert a claim against the Box Hill Defendants for purported violations of consumer protection statutes in Massachusetts, including

¹⁹ See *id.*, 64:7–65:1, excerpts attached as **Exhibit 7**.

²⁰ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

Mass. Gen. Laws Ann. Ch. 93A, et seq. Massachusetts law is clear, however, that there is no proper cause of action in the instant case against the Box Hill Defendants under Massachusetts General Law 93A. These Massachusetts laws are intended to protect *Massachusetts consumers* from unfair or deceptive trade practices. *See* Ch. 93A(2) (emphasis added). No relief can possibly be granted to the Plaintiffs in these actions based on this claim. As such, the Box Hill Defendants are entitled to summary judgment.

Section 11 governs jurisdiction of the Ch. 93A claim made by Plaintiff. It permits:

Any person who engages in the conduct of any trade or commerce and who suffers any loss...as a result of [another person's]...unfair or deceptive act or practice declared unlawful by section two...to bring an action **in the superior court** [of Massachusetts], **or in the housing court** [as provided in another statute unrelated to this claim], whether by way of original complaint, counterclaim, cross-claim or third-party action for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper...

A person may [also] assert a claim under this section in a **district court**, whether by way of original complaint, counterclaim, cross-claim or third-party action, for money damages only...

See MGL Ch. 93A, Section 11 (emphasis added).

After analyzing the above text of the actual statute, it is clear that the Circuit Court for Baltimore County, Maryland, where these claims are made, does not enjoy subject matter jurisdiction over a Ch. 93A claim. Section 11 clearly states that a Ch. 93A claim must be brought in a [Commonwealth of Massachusetts] “superior court,” “housing court,” or a “district court.” The instant actions were brought in the Maryland Circuit Court for Baltimore County. The fact that these cases were removed to this Court by action of the JPL for purposes of more efficient pretrial discovery, does not mean that these lawsuits were brought in this District Court.

If there is any doubt after reading Section 11 that the Circuit Court for Baltimore County lacks subject matter jurisdiction over Plaintiff's Ch. 93A claim, Section 7 further explains:

A person upon whom a notice is served pursuant to [a Ch. 93A investigation]²¹ shall comply with the terms thereof unless otherwise provided by the order of a court of the commonwealth.

...

The attorney general may file in the superior court of the county in which such person resides or has his principal place of business, or of Suffolk county if such person is a nonresident or has no principal place of business in the commonwealth, and serve upon such person, in the same manner as provided in section six, a petition for an order of such court for the enforcement of this section and section six.

...

See MGL Ch. 93A, Section 7 (emphasis added). Based on the actual statute itself, it is obvious that even enforcement of Ch. 93A and its parts is put in the hands of the Commonwealth and the Superior Court or another Court in the Commonwealth of Massachusetts.

There is no other interpretation of 93A except that it does not apply to the parties in this case. It only applies to trade or commerce directly or indirectly affecting the *people of [Massachusetts]*, Ch. 93A(1)(b), and to be handled by the Commonwealth of Massachusetts. This action was filed only by Maryland plaintiffs against Maryland defendants in a Maryland state court. It is undisputed that Defendant Dr. Bhambhani resides only in Maryland and that she is a physician licensed to practice in Maryland (not Massachusetts). Defendants Box Hill Surgery Center and Ritu T. Bhambhani, M.D., LLC, are both Maryland corporations. It is also undisputed that Plaintiffs are not residents of Massachusetts. The Box Hill Defendants are alleged to have sold or distributed MPA in their possession in Maryland to Maryland patients in the Box Hill Surgery Center facility, which is physically located in Maryland. The Plaintiff is alleged to have suffered injury in (or from care in) Maryland. To the extent that treatment was required for the patient

²¹ Section 7 refers to Section 6 of MGL Ch. 93A, which addresses Massachusetts law enforcements' ability to enforce Ch. 93A if a person does not comply with an investigation into the alleged violation.

Plaintiffs in these cases, it largely occurred in Maryland. At the very least none of the care occurred in Massachusetts. Clearly, all of the injuries alleged in this action are to non-Massachusetts' consumers. Again, MGL Ch. 93A does not apply to these cases.

In instances when Section 11 does not apply, Section 9 may apply. However, Plaintiffs' assertions in this regard would be an effort to expand the grasp of MGL 93A in order to reach the parties in this case who have absolutely no relation to Massachusetts' consumers. An examination of that anticipated assertion shows that Section 9 does not save Plaintiff's 93A claim either.

While not conceding that Section 9 even applies in this instance, Plaintiff's claim still fails under Section 9 even if the reach of Section 9 is considered. Clarification is found in *Snyder v. ADS Aviation Maintenance*, 2000 Mass.Super. LEXIS 5 at *20 (Jan. 10, 2000), curiously cited by Plaintiffs' counsel and/or the PSC in their opposition to the Box Hill Defendants' motion to dismiss years ago. *Snyder* maintains that jurisdiction under Section 9 of Ch. 93A is determined by the Massachusetts Long-arm Statute. *See Snyder* (quoting M.C. Gilleran, The Law of Chapter 93A, § 7:4 (1989 and Supp. 1999). More precisely, the only long-arm statute section that applies is Ch. 223A, § 3(d). *See Snyder, supra.* Ch. 223A, § 3(d) provides, in pertinent part, that:

A court may exercise personal jurisdiction over a person...as to a cause of action...arising from the person's...causing tortious injury in this commonwealth by an act...outside this commonwealth if he regularly...engages in...or derives substantial revenue from goods or services rendered in this commonwealth.

The Plaintiff bears the burden of establishing sufficient facts upon which to predicate personal jurisdiction over the Defendants under the Commonwealth's long-arm statute. *See Tatro v. Manor Care, Inc.*, 416 Mass. 763, 767 (1994). They have not done so. The first distinct element under section 3(d) requires a plaintiff to demonstrate that a defendant's act or omission caused a tortious injury inside Massachusetts. *Cunningham v. Adrox, Inc.*, 40 Mass. App. Ct. 279, 281 (1996) (emphasis added); *see also Snyder, supra.* Unlike in *Snyder*, where four individuals suffered injuries and died from a plane crash in Massachusetts, Plaintiff in the instant case suffered

a tortious injury in Maryland after contracting meningitis from medical care in Maryland. The services offered by the Defendants to the Plaintiffs did not even occur in Massachusetts. Moreover, the claim was not even made in the proper Court or by the proper person as addressed above.

Having failed the first element, let alone failing to meet their burden of proof, Plaintiffs' Massachusetts consumer protection claims against the Box Hill Defendants, even under Section 9, also fail. As such, there is no need to consider the second prong of the test involving contacts and derivation of business in Massachusetts, although that element also favors the Box Hill Defendants.

Plaintiff filed this action in the Circuit Court for Baltimore County, Maryland, but did not even plead a basis for jurisdiction of a Massachusetts state law, let alone establish any evidence during discovery to suggest that this Massachusetts law even applies. In fact, as explained above, the language of Ch. 93A does not allow this cause of action to continue against the Box Hill Defendants. Further, Plaintiff is unable to state or prove a claim under either Section 11 or Section 9 of MGL Ch. 93A upon which relief can be granted.

Based on all of the above, Defendants are entitled to judgment as a matter of law as to Count 9.²²

²² The MDL Court in its Memorandum of Decision as to Defendants' Motion to Dismiss in these actions nearly 2 years ago did not dismiss the Massachusetts consumer protection claim. *See* Ex. 1, pp. 6-7. That should not affect the outcome of this motion for summary judgment here. The Court's reasoning suggested that the so-called Massachusetts consumer to which these allegations of fraud had an injurious effect was NECC. However, NECC is not a Massachusetts consumer. They manufactured the contaminated MPA and sold it to health care providers. In fact, they were not even considered a "legal person" in the eyes of Massachusetts law, pursuant to Ch. 93A, § 2, at the time that this action was filed in Baltimore County Circuit Court. They were dissolved and the bankruptcy was confirmed and concluded. Moreover, NECC is not an aggrieved party in this lawsuit—their actions contributed to the contamination. Their owner and chief pharmacist, Barry Cadden was convicted in this Court of various counts of fraud. Most importantly, however, the Circuit Court for Baltimore County Maryland is not a proper court to bring a Ch. 93A claim. As such, the outcome should be different in the instant motion.

V. CONCLUSION

The claims analyzed above must be dismissed as a matter of law according to the Federal Rules of Civil Procedure and the other applicable law as outlined above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2017, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby
Gregory K. Kirby, Esq.